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Group 3700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mazzei EXAMINER: Lindsey, Rodney M.

Filed: 04/09/2000

Group Art Unit: 3765

Serial Number: 09/545,794

For: PROTECTIVE CUSHION AND COOPERATIVELY ENGAGEABLE HELMET CASING
FOR ANESTHETIZED PATIENT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

IN THE DRAWINGS

Proposed Drawing corrections are attached to add numerals 38,
39, 56, and 82. Formal drawing changes can follow, subject the
Examiner's approval.

IN THE SPECIFICATION

At page 21, line 14 of the specification, please delete the
number "35" and insert --59--.

At page 27, line 18 of the specification, please delete the
number "29" and insert --39--.

At page 38, line 10 of the specification, after the word
"aperture" please delete the letter "c" and insert --37--.

At page 38, line 11 of the specification, after the word
"aperture" please delete the number "36" and insert --29--.

At page 38, line 15 of the specification, please delete the word "nasal" and insert the word --nose--.

IN THE CLAIMS

Please amend the claim follows:

What is claimed is:

1. (amended) A protective helmet apparatus for providing patient cranial support during surgery, which may be assembled from a plurality of cooperatively engageable components of differing dimensions for achieving optimum fit and pressure diffusion upon face of the intended helmet wearer comprising:

a cushion, said cushion having a front portion and two cushion sidewalls extending upward from said front portion, said cushion having an interior surface and an exterior surface;

the interior surface of said cushion dimensioned to accommodate the facial structure of a human being;

at least one cushion ocular aperture in said cushion communicating laterally across said front portion and continuing up [at least one of] both of said two cushion sidewalls, said ocular aperture providing communication between said interior surface and said exterior surface;

a viewing passage formed by said cushion ocular aperture, said viewing passage providing a view through [at least one of]

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said cushion sidewalls, wherein [the] one of the two eyes [and facial temple area and the eye] of a patient wearing said cushion while in the prone position, may be seen though said viewing passage from a position adjacent to [at least one] either of said [sides] two cushion sidewalls, thereby allowing both of said patients eyes to be viewed through said viewing passage.

B
2. (amended) The device as in claim 1 wherein said exterior surface of said cushion is dimensioned for cooperative registered engagement with the interior of a helmet casing [whereby] wherein said cushion is [removably] interchangeably positionable [on] to either one of a first position cooperatively engaged with a helmet casing or a second position with said exterior surface of said cushion supported on a mounting surface, [in a] whereby said cushion may be used either in said first position or said second position to provide support to the head of a patient undergoing surgery.

3. (amended) The protective helmet apparatus as defined in claim 2 further comprising:

a helmet casing for use in combination with said cushion, said helmet casing having a casing front wall and two casing sidewalls, each of said casing sidewalls attached at a first edge to said casing front wall and extending generally vertically therefrom to an upper edge of said sidewalls, said helmet casing having a casing interior surface and a casing exterior surface;

means for registered cooperative engagement of said cushion with said helmet casing;

at least one casing ocular aperture in said helmet casing communicating between said casing interior surface and said casing exterior surface, said casing ocular aperture shaped substantially similar to said cushion ocular aperture, and positioned in said helmet casing to substantially align with said cushion ocular aperture when said cushion is in said registered cooperative engagement with said helmet casing, whereby either of said eyes of a patient wearing said cushion may be seen through the respective adjacent casing sidewall of said helmet casing [said viewing passage extends through said casing ocular aperture] when said cushion is in registered cooperative engagement with said helmet casing; and

means for removable attachment of said helmet casing to said [a fixed position on a] mounting surface.

4. (amended) The protective helmet apparatus as defined in claim 3 wherein said means for registered cooperative engagement of said cushion with said helmet casing comprises one or a combination of means for registered cooperative engagement from a group consisting of, said casing interior surface dimensioned for frictional engagement with said exterior surface of said cushion, adhesive, a lip positioned on said cushion in a position for

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operative engagement with the upper edges of said casing sidewalls, and registration pins affixed to said exterior surface of said cushion cooperatively engageable with registration apertures located in said interior surface of said helmet casing.

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6. (amended) The protective helmet apparatus as defined in claim 3 wherein said means for removable attachment of said helmet casing to said mounting surface comprises a plurality of legs extending from the exterior surface of said helmet casing, the distal ends of said plurality of legs configured for cooperative engagement with a mount, said mount attachable to said mounting surface.

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8. (amended) The protective helmet apparatus as defined in claim 7 further comprising a casing chin aperture in said casing front wall said casing chin aperture communicating between said casing interior surface and said casing exterior surface, said casing chin aperture shaped substantially similar in shape to said cushion chin aperture and positioned to substantially align with said cushion chin aperture when said cushion is in said registered engagement with said helmet casing; and

 said nasal cavity communicating from said interior surface of said cushion to said exterior surface of said casing thereby forming a tube passageway.

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14. (amended) The protective helmet apparatus as defined in claim 11 wherein said mount additionally comprises, a mirrored surface affixed to said mounting plate, thereby providing a means for upright individuals standing adjacent to said protective [head] helmet apparatus to view the ocular area of the patients face reflected in the mirrored surface by looking downward at said mirrored surface.

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35 U.S.C. §102 per Hartunian

The Examiner's reasons for rejecting claims 1, and 2, as being anticipated by Hartunian under 35 U.S.C. §102 are respectfully traversed.

Hartunian while disclosing a front portion and two sidewalls, and with two embodiments. The first embodiment (10), as taught, fails to show or teach any elongated opening (82) and teaches only two openings (52 and 54) which communicate through the sidewalls of the device (10) on the front portion (16). This embodiment is thus incapable of providing a view of the patient's eyes through the sidewall since the eyes would be covered by the sidewall.

The second embodiment of Hartunian, only teaches the use of a single opening (82) which is essentially the extension of opening (52) to the top of the sidewall (20) which interrupts one sidewall to allow viewing of one eye of a patient.

However the major reason the opening (82) is formed and separates the sidewall, is to allow the patient to be fitted with an endotracheal air tube (55) while face up, and then be rotated to the face down position and allow the air tube (55) to rotate into the opening (82) without disconnecting it from the patient. (page 11, lines 30-40) Thus, it is imperative that openings (82) cut the entire sidewall (20) in half, as taught by Hartunian.

Since the entire sidewall (20) is separated into two pieces by the opening (82) the only material holding the device itself together is the small strip of material in the opposite sidewall

X

(24) just above opening (54). Consequently, it is impossible for the device as taught by Hartunian, to extend an ocular viewing slot as taught by Applicant, up both sidewalls, (20 and 24) to allow viewing of either of both eyes of the patient through the formed ocular slot as taught by Applicant.

Further, nowhere in Hartunian does it teach or suggest, extending a second opening (82) in the opposite sidewall from the first. There is a good reason it lacks this element. If the Hartunian device using the opening (82) as taught, provided for a second void or opening (82) up the opposite sidewall, it would cause the Hartunian device to separate into two pieces and render it inoperable.

Also, Applicant's device provides the surgeon with the option to use the cushion by itself, as claimed in claim 1 and 2 or in combination with the helmet. As noted on page 35 line 13 of the specification, The one piece facial cushion offers an additional benefit in that in some cases it might be used without the helmet casing. Use without the casing might occur when an especially low mount of the patient's head is desired for posture or for the surgical procedure, or, in an emergency or other situation where the additional support and utility of the in-line helmet casing is not required. It was further noted that use of the facial cushion by itself does provide the easy side viewing of the patients eyes through the elongated ocular cushion aperture and still provides improved support and padding to the patient's head. Thus as



claimed in claim 2, the device provides the user an option to interface or not to interface with a casing depending, an element neither taught nor mentioned in the cited art.

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984).

DRAFTING ATTACHMENT

As clearly shown, in addition to the optional mounting ability of applicant's device, Hartunian lacks an ocular slot traversing the front portion and continuing up both sidewalls to a position where either of either of both eyes may be viewed through either of both respective sidewalls, as taught and claimed by Applicant. In fact as shown, Hartunian teaches away from such a device by in one embodiment with no opening on the side wall and in the other embodiment with the sidewall opening to become a void up the entire sidewall in order to provide for patient rotation. The opening cannot then be continued up the other sidewall or it would become a void down the center of the device cutting it in two.

As such, the Hartunian citation lacks elements and function of Applicant's claimed device and the Examiner's objections under Section 102 as to claims 1 and 2 are respectfully traversed.

X

REMARKS

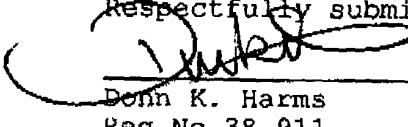
The drawings and specification have been amended to more clearly show the patentable subject matter of the device and to respectfully travers the objections under Section 112.

Claim 1, has been amended to more clearly define the subject matter of the invention as have claims 2,3,4,6,8, 14, and 19.

Applicant's device as clearly claimed in amended claim 1 has an ocular slot extending up both sidewalls to allow viewing of either of both eyes of the patient which is not claimed or taught by the cited reference which would be rendered inoperative in such a configuration. Applicant's device also is optionally positionable in or out of a casing which the prior art fails to teach or mention. As such claim 1 should now be allowable as should claims 2-22 which depend from claim 1.

Should the Examiner have any further questions or concerns the Examiner wishes to address by telephone or otherwise, or should the Examiner have suggestions to more clearly define the subject matter of the claims to more clearly define the patentable subject matter, the Applicant's attorney would be most receptive to such.

Respectfully submitted,


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CLEAN COPY OF AMENDED CLAIMS

1. A protective helmet apparatus for providing patient cranial support during surgery, which may be assembled from a plurality of cooperatively engageable components of differing dimensions for achieving optimum fit and pressure diffusion upon face of the intended helmet wearer comprising:

 a cushion, said cushion having a front portion and two cushion sidewalls extending upward from said front portion, said cushion having an interior surface and an exterior surface;

 said interior surface of said cushion dimensioned to accommodate the facial structure of a human being;

 at least one cushion ocular aperture in said cushion communicating laterally across said front portion and continuing up both of said two cushion sidewalls, said ocular aperture providing communication between said interior surface and said exterior surface;

 a viewing passage formed by said cushion ocular aperture, said viewing passage providing a view through said cushion sidewalls, wherein one of the two eyes of a patient wearing said cushion while in the prone position, may be seen though said viewing passage from a position adjacent to either of said two cushion sidewalls, thereby allowing both of said patients eyes to be viewed through said viewing passage.

2. The device as in claim 1 wherein said exterior surface of said cushion is dimensioned for cooperative registered engagement with the interior of a helmet casing wherein said cushion is interchangeably positionable to either one of a first position cooperatively engaged with a helmet casing or a second position with said exterior surface of said cushion supported on a mounting surface, whereby said cushion may be used either in said first position or said second position to provide support to the head of a patient undergoing surgery.

3. The protective helmet apparatus as defined in claim 2 further comprising:

a helmet casing for use in combination with said cushion, said helmet casing having a casing front wall and two casing sidewalls, each of said casing sidewalls attached at a first edge to said casing front wall and extending generally vertically therefrom to an upper edge of said sidewalls, said helmet casing having a casing interior surface and a casing exterior surface;

means for registered cooperative engagement of said cushion with said helmet casing;

at least one casing ocular aperture in said helmet casing communicating between said casing interior surface and said casing exterior surface, said casing ocular aperture shaped substantially similar to said cushion ocular aperture, and positioned in said

helmet casing to substantially align with said cushion ocular aperture when said cushion is in said registered cooperative engagement with said helmet casing, whereby either of said eyes of a patient wearing said cushion may be seen through the respective adjacent casing sidewall of said helmet casing when said cushion is in registered cooperative engagement with said helmet casing; and

means for removable attachment of said helmet casing to said mounting surface.

4. The protective helmet apparatus as defined in claim 3 wherein said means for registered cooperative engagement of said cushion with said helmet casing comprises one or a combination of means for registered cooperative engagement from a group consisting of, said casing interior surface dimensioned for frictional engagement with said exterior surface of said cushion, adhesive, a lip positioned on said cushion in a position for operative engagement with the upper edges of said casing sidewalls, and registration pins affixed to said exterior surface of said cushion cooperatively engageable with registration apertures located in said interior surface of said helmet casing.

6. The protective helmet apparatus as defined in claim 3 wherein said means for removable attachment of said helmet casing to said mounting surface comprises a plurality of legs extending from the exterior surface of said helmet casing, the distal ends of said plurality of legs configured for cooperative engagement with a mount, said mount attachable to said mounting surface.

8. The protective helmet apparatus as defined in claim 7 further comprising a casing chin aperture in said casing front wall said casing chin aperture communicating between said casing interior surface and said casing exterior surface, said casing chin aperture shaped substantially similar in shape to said cushion chin aperture and positioned to substantially align with said cushion chin aperture when said cushion is in said registered engagement with said helmet casing; and

 said nasal cavity communicating from said interior surface of said cushion to said exterior surface of said casing thereby forming a tube passageway.

14. The protective helmet apparatus as defined in claim 11 wherein said mount additionally comprises, a mirrored surface affixed to said mounting plate, thereby providing a means for upright individuals standing adjacent to said protective helmet apparatus to view the ocular area of the patients face reflected in the mirrored surface by looking downward at said mirrored surface.

19. The protective helmet apparatus as defined in claim 17 wherein said means for heating the head of a patient is an electrical resistive heating element mounted on a blanket which is attachable to one of said upper edges of said casing side walls, whereby said blanket may be folded over the patients head when said head is operatively occupying said protective helmet apparatus.

23. The protective helmet apparatus as defined in claim 3 additionally comprising:

means for height adjustment of said helmet casing above said mounting surface.

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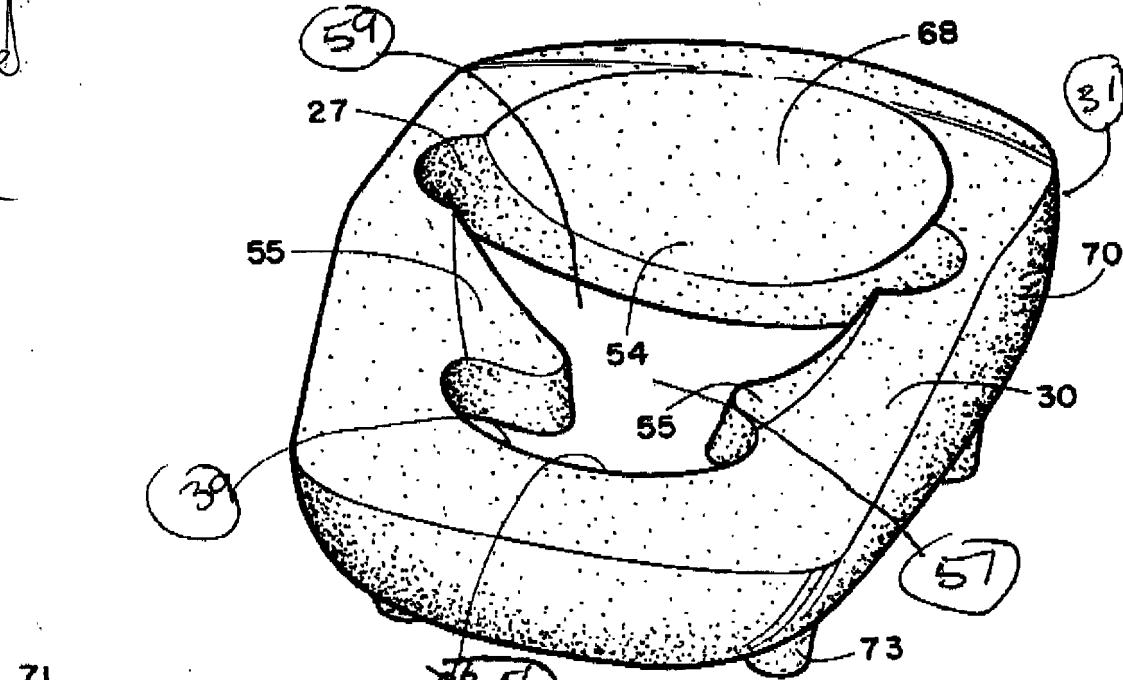


FIGURE 9

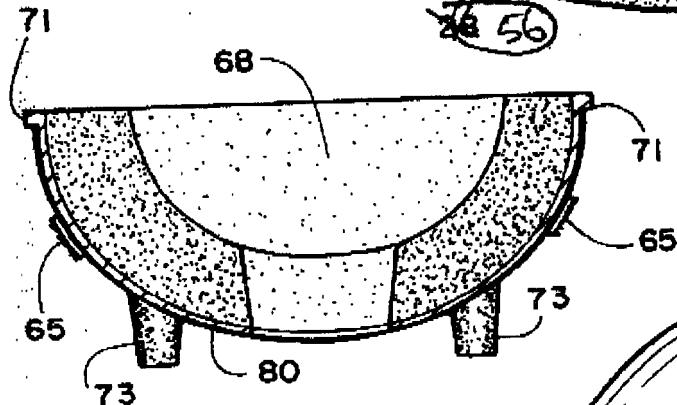


FIGURE 10

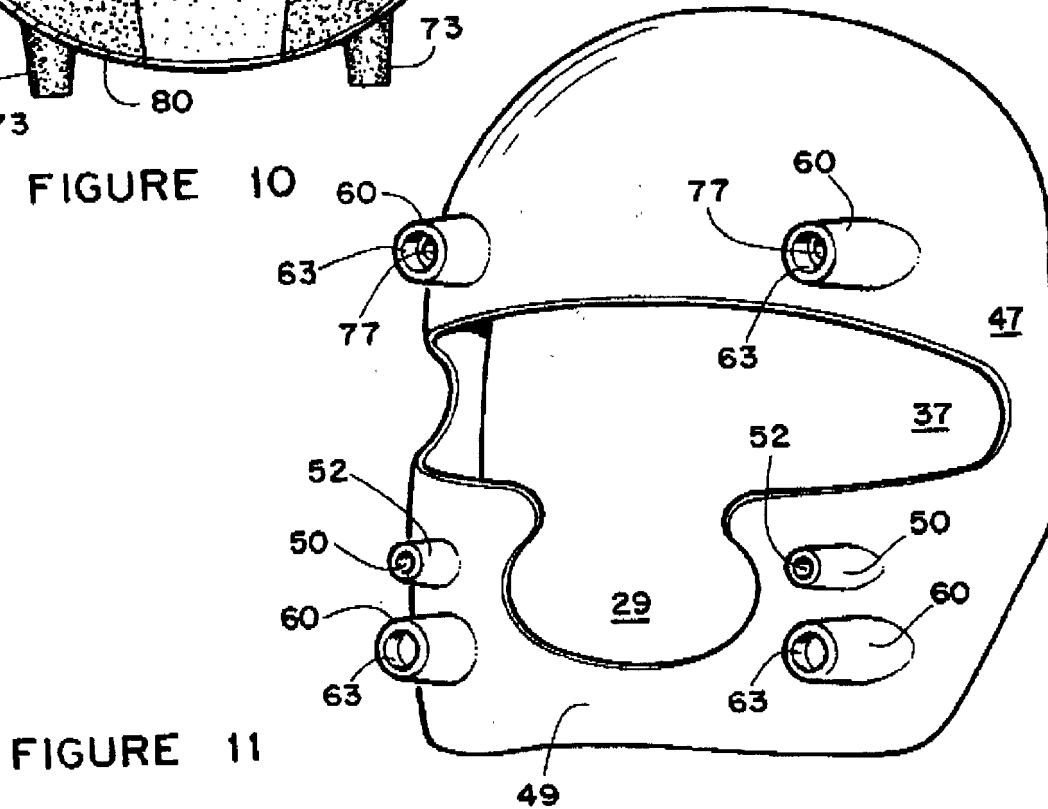


FIGURE 11

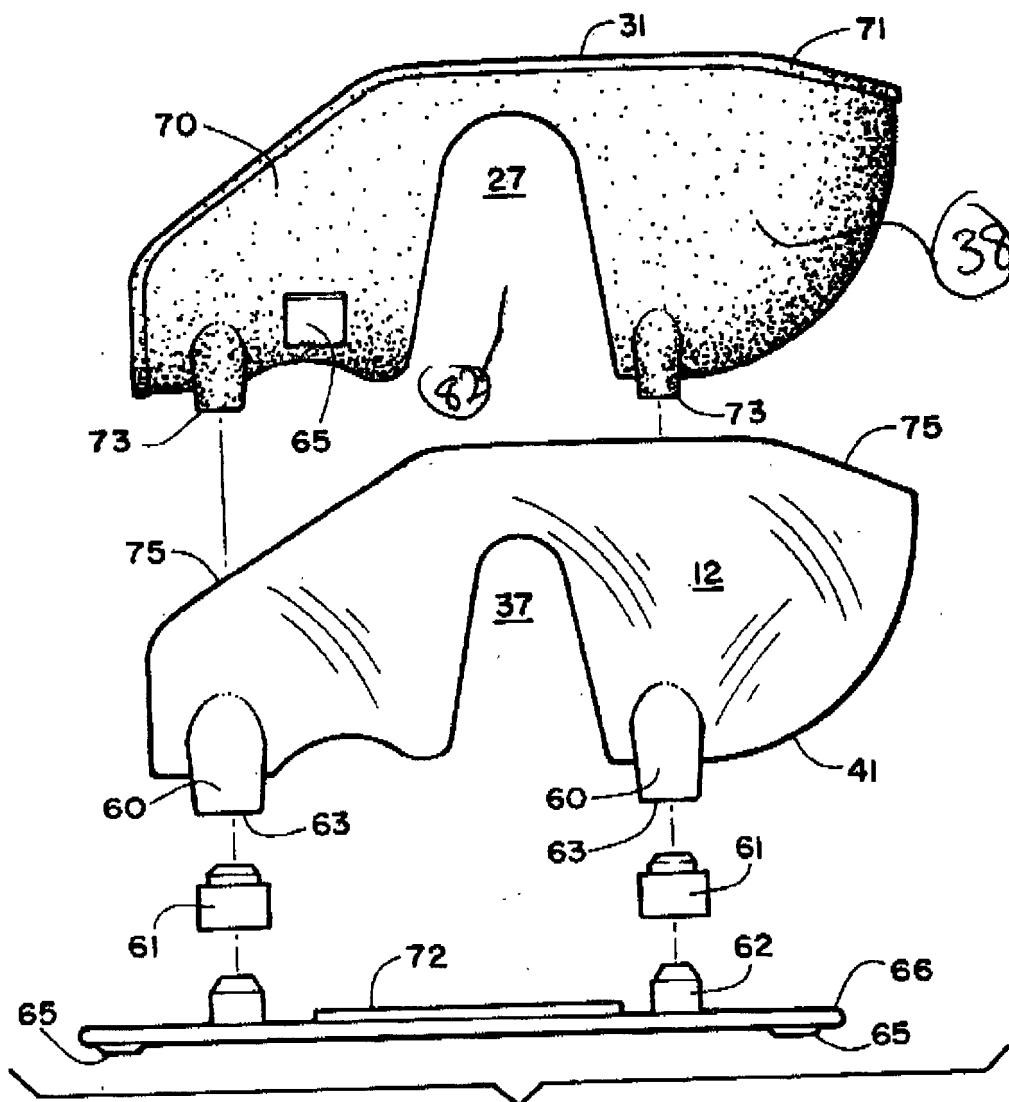


FIGURE 7

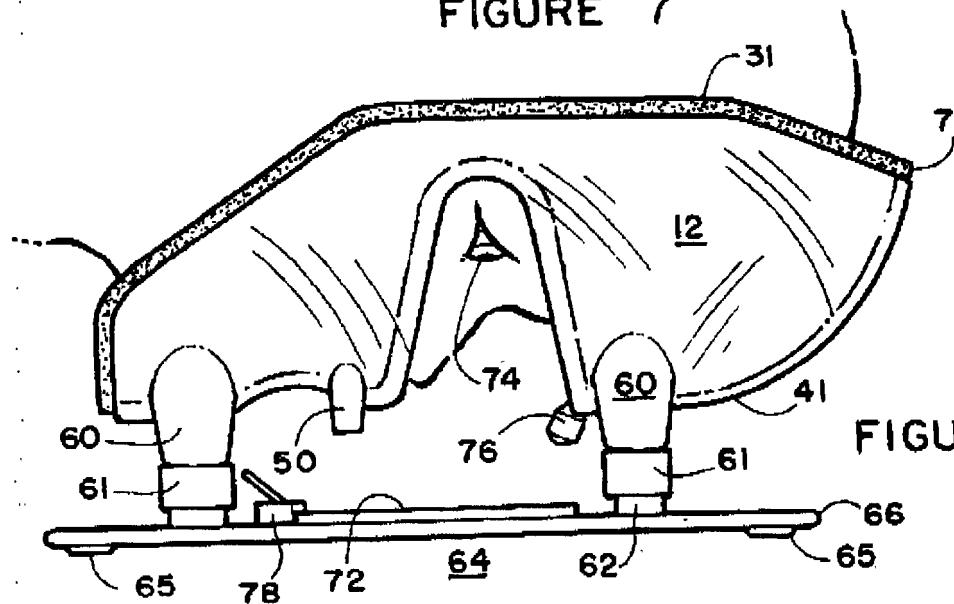


FIGURE 8